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Adreas F. Schaub

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EXAMINER

FRAZIER, BARBARA S

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/501,984	SCHAUB, ADREAS F.	
	<b>Examiner</b>	<b>Art Unit</b>	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 5) ☒ Claim(s) 28-37,39 and 41-47 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 28-37,39 and 41-47 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/12/11</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Status of claims***

1. Claims 28-37, 39, and 41-47 are pending in this application.
2. Addition of new claims 45-47 is acknowledged.
3. Claims 28-37, 39, and 41-47 are examined.

### ***Claim Rejections - 35 USC § 112***

4. The rejection of claim 44 under 35 U.S.C. 112, first paragraph is withdrawn in view of Applicant's amendment to claim 44.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 28, 30, 32, 34, 37, 39, 41, 42, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara et al (US Patent 3,971,848, "Kasahara '848", previously cited) in view of Van Leuven (US Patent 4,267,168, previously cited) as evidenced by Muller et al (US Patent 5,624,903, previously cited) and Bringloe (US Patent 4,765,478, previously cited).**

The claimed invention is drawn to a method for reducing the frictional force between an item to be delivered and a birth canal of a mother in human vaginal child birthing, which comprises the steps of applying effective amounts of an organic lubricant comprising a polyacrylic acid; isotonicizing substances; a humectant; and no alkali metal salts of metaphosphates; wherein said composition is in the form of a paste, gel, cream, suppository, or foam; according to the steps and functional limitations recited in claim 28 (see claim 28). Also claimed is a method of reducing injuries to a mother's birth canal, reducing the risk of episiotomy, reducing the risk of vaginal interventions, or reducing the risk of cesarean sections during human child birthing, which comprises the same steps (see claim 45).

Kasahara '848 teaches a composition having lubricating property comprising fucoidin and alginic acid (abstract) and does not contain alkali metal metaphosphates. The composition may be used to lubricate the birth canal in human bodies to facilitate the delivery of the fetus (col. 5, lines 16-32). The composition may be optionally mixed with sodium polyacrylate and carboxymethyl cellulose (col. 5, lines 39-42). Kasahara '848 further teaches that the addition of sodium polyacrylate is preferable to afford lubrication at the time of parturition, and the addition of a viscous substance (i.e., a thickener) such as carboxymethyl cellulose results in a composition having a further improved lubrication (col. 2, lines 21-36), and therefore one skilled in the art would be motivated to include said substances in the composition. Kasahara '848 further teaches that, in order to heighten the solubility of the compositions, it is preferred at the time of application to blend the compositions with glucose (col. 5, lines 43-45). Glucose is an

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isotonicizing substance, as evidenced by Muller et al, which teaches that glucose is an isotonicizing agent (see col. 4, lines 9-10).

While Kasahara '848 teaches the presence of a polyacrylic acid and glucose (isotonicizing substance), Kasahara '848 is silent with respect to the presence of a humectant in the composition.

Van Leuven teaches that the humectants propylene glycol and glycerine (i.e., glycerol) are used in compositions which act as lubricants to be used during delivery at the time of birth (abstract).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add the humectants propylene glycol and/or glycerine to the composition of Kasahara '848; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because the addition of said humectant(s) provides the benefits of a very soothing action on tender tissue, as with glycerin, and some bacteriocidal activity, as with propylene glycol, as taught by Van Leuven (see col. 6, lines 1-2 and col. 5, lines 47-49, respectively). One would reasonably expect success from the addition of propylene glycol and/or glycerin as taught by Van Leuven to the composition of Kasahara '848 because both references are drawn to compositions useful for lubricating the birth canal during delivery.

Regarding the form of the composition, Kasahara '848 teaches that the composition is a "mucous, thready composition having lubricating property" (col. 2, lines 7-8) and that carboxymethyl cellulose is a viscous substance (col. 2, lines 31-35), and therefore one skilled in the art would reasonably expect the composition to be in the

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form of a gel; as further evidence, Bringloe teaches that carboxymethyl cellulose is a known gelling agent in topical compositions (see col. 3, lines 46-53), which would also favor the formation of a gel composition.

Regarding the limitations of reducing injuries to a mother's birth canal, the risk of episiotomy, the risk of vaginal interventions, or the risk of cesarean sections (claims 28 and 45), Kasahara '848 teaches that, in clinical experiments made on pregnant women, the use of its composition allows for the delivery of a fetus to be “greatly facilitated **with effects of preventing damages on a birth canal**, reducing the pressure imposed on the neonate and releasing the mother from labour pains” (col. 5, lines 22-32).

Therefore, one skilled in the art would reasonably expect the composition of the combined references to reduce injuries to a mother's birth canal, the risk of episiotomy, the risk of vaginal interventions, or the risk of cesarean sections, absent evidence to the contrary.

Regarding the application steps of the composition (claims 28, 37, 39, 41, and 45), Kasahara '848 exemplify application of the composition just before parturition (col. 5, lines 27-30). The phrase “just before parturition” reasonably reads on before labor or dilation begins, as well as during the dilation phase. While Kasahara '848 is silent with respect to multiple application steps as now recited in amended claim 28, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the same composition in multiple steps, since said steps amount to design choice and within the purview of the skilled artisan. Regarding forming a lubricant layer, Kasahara '848 teaches that the composition is injected into the vagina

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(i.e., applied to the birth canal; see col. 5, lines 16-32) and that the substances are not likely to escape between the frictional interfaces of the animals (col. 2, lines 25-30).

Therefore, one skilled in the art would reasonably expect a lubricant layer to be formed between the birth canal surface and the item to be delivered.

Regarding claim 30, Kasahara '848 teaches that the viscous substance (thickener) carboxymethyl cellulose may be added to the composition.

Regarding claim 32, Van Leuven teaches the humectants propylene glycol and glycerine (i.e., glycerol) are used in compositions which act as lubricants to be used during delivery at the time of birth (abstract).

Regarding claim 34, Kasahara '848 teaches that the composition to be used for lubricating the birth canal of humans comprises water (see col. 5, lines 21-32).

Regarding claim 42, Kasahara '848 teaches that the composition is injected into the vagina (i.e., applied to the birth canal; see col. 5, lines 16-32) and that the substances are not likely to escape between the frictional interfaces of the animals (col. 2, lines 25-30). Therefore, one skilled in the art would reasonably expect the composition to have a greater adhesion to the surface of the birth canal compared with the skin of the fetus.

**7. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara '848 in view of Van Leuven and evidenced by Muller and Bringloe as applied to claims 28, 30, 32, 34, 37, 39, 41, and 42 above, and further in view of JP 46-24256 ("JP '256", previously cited).**

Claim 29 of the claimed invention is drawn to the method of claim 28, wherein said polyacrylic acid is present in a concentration of from 0.25 to 5% by weight.

The invention of the combined references is delineated above (see paragraph 12).

The invention of the combined references is silent with respect to the amount of sodium polyacrylate in the composition.

JP '256 teaches that sodium polyacrylate is useful as a lubricant during birth, and that the lubricant does not lose its activity when diluted to 0.2-0.3% concentration. This amount overlaps that of the claimed invention. One skilled in the art would be motivated to manipulate the amount of sodium polyacrylate from within said ranges by routine experimentation, in order to optimize the lubricity of the resultant composition.

**8. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara '848 in view of Van Leuven and evidenced by Muller and Bringloe as applied to claims 28, 30, 32, 34, 37, 39, 41, and 42 above, and further in view of Behl et al (US Patent 5,580,574).**

Claim 31 of the claimed invention is drawn to the method of claim 30, wherein said cellulose is present in a concentration of from 1 to 3% by weight.

The invention of the combined references is delineated above (see paragraph 12). As noted above, Kasahara '848 teaches that carboxymethyl cellulose may be added to the composition (col. 5, lines 39-40).



The invention of the combined references is silent with respect to the amount of cellulose in the composition.

Behl et al teach pharmaceutical compositions for transdermal delivery (abstract). The compositions include gelling agents in amounts sufficient to obtain a desired consistency of the gel; amounts of carboxymethyl cellulose are preferably in the range of from about 2 to 5 percent by weight of the composition (col. 2, line 59 - col. 3, line 5). This amount overlaps that of the claimed invention. One skilled in the art of topical compositions would be motivated to manipulate the amount of carboxymethylcellulose taught in Kasahara '848 from within said ranges by routine experimentation, in order to optimize the desired consistency of gel as taught by Behl et al.

**9. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara '848 in view of Van Leuven and evidenced by Muller and Bringloe as applied to claims 28, 30, 32, 34, 37, 39, 41, and 42 above, and further in view of Roder et al (US Patent 6,217,885).**

Claim 33 of the claimed invention is drawn to the method of claim 28, wherein said composition comprises carob flours in a concentration of from 0.5 to 3% (see claim 33).

The invention of the combined references is delineated above (see paragraph 11). Kasahara '848 teaches that, when viscous substances such as alkali salt of alginic acid, gum Arabic and carboxymethyl cellulose are added, the resulting composition has a further improved lubrication (col. 2, lines 29-36).

The invention of the combined references does not specifically teach that one of the viscous substances may be carob flour.

Roder et al teach cosmetic and/or pharmaceutical compositions for use on human or animal skin (abstract), which may be in the form of gels, creams or foams (col. 3, lines 46-47), and wherein preferably 0.1 to 2% of thickeners and gelling agents can be employed, which include cellulose derivatives, alginates, and carob bean flour (col. 6, lines 38-42). The amount of gelling agent employed overlaps that of the claimed invention; one skilled in the art would be motivated to manipulate the amount of gelling agent from within said ranges by routine experimentation, in order to optimize the consistency of the resultant composition.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select carob flour as one of the thickeners in the composition of the combined references; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because alginates and cellulose derivatives, and carob flour, are all known thickeners and gelling agents in topical compositions for human or animal skin as taught by Roder, and therefore are functionally equivalent to one another. Therefore, it would be well within the purview of the skilled artisan to choose either compound as one of the thickeners of the composition of the combined references, since the prior art establishes the functional equivalency of carob flour and cellulose derivatives and alginates.

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**10. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara '848 in view of Van Leuven and evidenced by Muller and Bringloe as applied to claims 28, 30, 32, 34, 37, 39, 41, and 42 above, and further in view of Kasahara et al (US Patent 3,814,797, "Kasahara '797", cited by Applicants in the IDS filed 7/21/04).**

Claims 35 and 36 of the claimed invention are drawn to the method of claim 28, wherein between 5 to 200 mL (claim 35) or between 10 to 100 mL (claim 36) of said composition is introduced into birth canal.

The invention of the combined references is delineated above (see paragraph 12).

The invention of the combined references is silent with respect to the amount of composition introduced into the birth canal.

Kasahara '797 teaches aqueous lubricating compositions for imparting lubricity to the parts of living bodies (abstract). The aqueous compositions may be applied to human beings (col. 3, lines 50-51). For use in human delivery, Kasahara '797 exemplify an amount of 100 mL of the composition (see Example 2, column 4).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use an amount of the composition of the combined references of 100 mL; thus arriving at the claimed invention. When determining an appropriate amount, one skilled in the art would look for guidance from the teachings in the prior art of other lubricant compositions used in human delivery, such as Kasahara '797. Therefore, one skilled in the art would be motivated to select an amount of

lubricating composition according to the teachings of Kasahara '797, absent evidence to the contrary.

**11. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara '848 in view of Van Leuven and evidenced by Muller and Bringloe as applied to claims 28, 30, 32, 34, 37, 39, 41, and 42 above, and further evidenced by Dettmar (US Patent 4,652,446).**

Claim 43 of the claimed invention is drawn to the method of claim 28, wherein the polyacrylic acid is a crosslinked polyacrylic acid.

The invention of the combined references is delineated above (see paragraph 11). As noted above, Kasahara '848 teaches that the composition may be mixed with sodium polyacrylate (col. 5, lines 39-42). The term "sodium polyacrylate" denotes the sodium salt of a polyacrylic acid which may be linear or cross-linked; as evidence, Dettmar teaches that the phrase "sodium polyacrylate" denotes the sodium salt of a polyacrylic acid which may be linear or cross-linked in mucosal-protecting compositions (col. 1, lines 44-46).

### ***Response to Arguments***

12. Applicant's arguments filed 12 August 2011 have been fully considered but they are not persuasive.

Applicant argues that further objective evidence has been submitted to demonstrate an art-recognized problem existed for a long period of time without solution, and that claim 28 has been amended to be commensurate in scope therewith.

Applicant's amendments to claim 28 and evidence submitted 12 August 2011 have been fully considered, but are not sufficient for overcoming the rejection.

Applicant argues that its first article submitted (Stamp et al.) and third article submitted (Albers 1995) come to the conclusion that the practice of perineal massage does not increase likelihood of an intact perineum or reduce the risk of pain, dyspareunia, or urinary and faecal problems (Stamp et al.), and that neither the use of warm compresses or perineal massage with lubricant late in the second stage of labor increased or decreased the overall rates of genital tract trauma (Albers 1995). However, the teachings of Kasahara '848 are not directed to the practice of perineal massage, but rather lubricating the birth canal (e.g., see col. 5, lines 16-32). The claimed invention is also directed to lubricating the birth canal. Therefore, Stamp's and Albers 1995's teachings regarding perineal massage are not sufficient for overcoming the rejection, since the process of Kasahara '848 and the claimed invention are both directed to lubricating the birth canal, while the teachings of Stamp et al. and Albers 1995 are directed to perineal massage. While Applicant's second article submitted (Albers 1996) found that use of oils or lubricants (and the lithotomy position) increased lacerations (abstract), this also appears to be in the context of perineal massage (e.g., page 271, top of 2<sup>nd</sup> column), and not lubricating the birth canal. Additionally, while Applicant's fourth and fifth articles submitted (Schaub and Dianatal Report) appear to

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demonstrate use of the claimed invention for increasing perineal integrity, including reducing vaginal tear rates, episiotomy rates, vaginal operative procedure/intervention rates, and emergency cesarean rates, this evidence is not sufficient for overcoming the rejection, since the invention of the combined references already teaches that use of a composition of the claimed invention can be used on pregnant women to greatly facilitate the delivery of a fetus with effects of preventing damages on a birth canal (col. 5, lines 16-32 of Kasahara '848).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Therefore, it is the Examiner's position that claim 28 is rendered obvious.

Dependent claims 28, 30, 32, 34, 37, 39, 41, and 42, and newly added claim 45, are also rendered obvious for reasons set forth herein.

Applicant has not presented additional arguments for claims 29, 31, 33, 35-36, and 43 apart from those presented for independent claim 28, and therefore these claims are also rendered obvious for reasons set forth herein.

**13. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Leuven (US Patent 4,267,168, previously cited) in view of JP 46-24256 ("JP '256", previously cited).**

Claim 44, as amended, is drawn to a method for reducing the frictional force between an item to be delivered and a birth canal of a mother in human vaginal child birthing, which comprises applying effective amounts of an organic lubricant composition comprising a lubricant film-forming combination consisting of water and at least two substances selected from the list recited in claim 44, and no alkali metal salts of metaphosphates; wherein said composition is in the form of a paste, gel, cream, suppository, or foam; according to the steps recited in claim 44 (see claim 44).

Van Leuven teaches compositions which act as lubricants to be used during delivery at the time of birth (abstract). The glycerine provides a soothing action on tender tissue, and is used in amounts which provide an adequate range of lubricity in the composition (col. 6, lines 1-7); therefore, the composition may comprise a lubricant consisting of glycerine. The composition can be used to aid in delivery of a baby at birth by being applied to vaginal tissue (i.e., the birth canal) of the baby's mother (col. 6, lines 53-54).

While Van Leuven teaches a composition comprising a lubricant consisting of glycerine to aid in the delivery of a baby at birth by being applied to vaginal tissue (i.e., the birth canal) of the baby's mother, Van Leuven does not specifically teach the use of a combination consisting of glycerine, polyacrylic acid, and water as the lubricant.

JP '256 teaches a lubricant consisting essentially of a polyacrylate (preferably sodium or ammonium) shows good lubricating properties, and is applied to the animals vagina by painting at the time of birth. The lubricant may be supplied as a water-soluble dust, and does not lose its activity when diluted to 0.2-0.3% concentration (see abstract), and therefore may be diluted with water.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add sodium polyacrylate and water lubricant to the glycerine lubricant of the composition of Van Leuven; thus arriving at the claimed invention. One skilled in the art would be motivated to do so, with a reasonable expectation of success, because the ingredients of sodium polyacrylate diluted in water is known to have good lubricating properties, and both compositions are useful for providing lubrication at the time of birth.

Regarding the application steps of the composition, Van Leuven teaches that the composition can be used to aid in delivery of a baby at birth by being applied to vaginal tissue (i.e., the birth canal) of the baby's mother (col. 6, lines 53-54). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the same composition in multiple steps, since said steps amount to design choice and within the purview of the skilled artisan.

Regarding forming a lubricant layer, Van Leuven teaches that the composition is useful as a lubricant to be used during delivery at the time of birth (e.g., see abstract), and therefore one skilled in the art would reasonably expect the composition to form a lubricant layer between the birth canal surface and the item to be delivered.



***Response to Arguments***

14. Applicant's arguments filed 12 August 2011 have been fully considered but they are not persuasive.

Applicant argues that Van Leuven's composition obligatorily includes a number compounds outside the scope of claim 44 that significantly influence the lubricating effect of Van Leuven's composition, such as, for example, dodecyl benzene sulfonic acid and propylene glycol. Applicant argues Van Leuven discloses a list of ingredients and discloses that sulfonic acid is essential to the lubricity and viscosity of the composition, citing col. 5, lines 5-15 of Van Leuven. Applicant also argues JP '256 is an aqueous solution, which would not form a lubricant film, according to standard practice for use in animal deliveries.

This argument is not persuasive. Regarding the use of dodecyl benzene sulfonic acid in Van Leuven, it is noted that claim 44 now recites "surface-active substances" at line 17 of claim 44, which would include dodecyl benzene sulfonic acid, since Van Leuven teaches dodecyl benzene sulfonic acid is widely used as a surface active agent common in many detergent compositions (col. 4, line 64 – col. 5, line 1). Regarding the use of propylene glycol, it is noted that Applicants do not argue why propylene glycol would be required for the lubricant effect of the composition; Van Leuven teaches that propylene glycol has some bacteriocidal activity which cooperates with that of the silver to enhance the biocidal activity of the composition (col. 5, lines 47-51), and therefore Van Leuven does not teach that propylene glycol is required for its lubricant activity.

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Regarding the teachings of JP '256, it is noted that JP '256 specifically teaches that its composition is a lubricant, and shows good lubricating and viscosity properties (see abstract), and therefore these arguments are also not persuasive.

Therefore, it is the Examiner's position that the claim is rendered obvious.

The following rejection is newly applied:

**15. Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Leuven (US Patent 4,267,168, previously cited) in view of JP 46-24256 ("JP '256", previously cited), as evidenced by Muller et al (US Patent 5,624,903, previously cited) and Yunis (US Patent 5,877,209).**

Newly added claims 46 and 47 are drawn to the method of claim 28, wherein the lubricating organic substance does not contain alginate (claim 46), or wherein the composition does not contain alginate (claim 47).

Van Leuven teaches compositions which act as lubricants to be used during delivery at the time of birth (abstract). The composition contains water, propylene glycol and glycerine (abstract and col. 5, lines 47-60). Glycerine is an isotonicizing substance, as evidenced by Muller, which generally teaches that glycerol (glycerine) is an isotonicizing substance (col. 4, lines 9-10). Propylene glycol and glycerine are humectants, as evidenced by Yunis, which generally teaches that typical humectants include glycerine and propylene glycol (col. 3, lines 18-19). The composition can be used to aid in delivery of a baby at birth by being applied to vaginal tissue (i.e., the birth canal) of the baby's mother (col. 6, lines 53-54).

While Van Leuven teaches a composition comprising isotonicizing agent and humectant to aid in the delivery of a baby at birth by being applied to vaginal tissue (i.e., the birth canal) of the baby's mother, Van Leuven does not specifically teach the inclusion of polyacrylic acid in said composition.

JP '256 teaches a lubricant consisting essentially of a polyacrylate (preferably sodium or ammonium) shows good lubricating properties, and is applied to the animals vagina by painting at the time of birth. The lubricant may be supplied as a water-soluble dust, and does not lose its activity when diluted to 0.2-0.3% concentration (see abstract), and therefore may be diluted with water.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add a polyacrylate to the composition of Van Leuven; thus arriving at the claimed invention. One skilled in the art would be motivated to do so, with a reasonable expectation of success, because the ingredients of a polyacrylate diluted in water is known to have good lubricating properties, and both compositions are useful for providing lubrication at the time of birth.

Regarding the limitations of reducing injuries to a mother's birth canal, the risk of episiotomy, the risk of vaginal interventions, or the risk of cesarean sections, Van Leuven teaches the composition can be used to aid in delivery of a baby at birth by being applied to vaginal tissue (i.e., the birth canal) of the baby's mother (col. 6, lines 53-54), and therefore one skilled in the art would reasonably expect such aid would result in reduced injuries and/or interventions during birthing, absent evidence to the contrary.

Regarding the application steps of the composition, Van Leuven teaches that the composition can be used to aid in delivery of a baby at birth by being applied to vaginal tissue (i.e., the birth canal) of the baby's mother (col. 6, lines 53-54). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the same composition in multiple steps, since said steps amount to design choice and within the purview of the skilled artisan.

Regarding forming a lubricant layer, Van Leuven teaches that the composition is useful as a lubricant to be used during delivery at the time of birth (e.g., see abstract), and can be used to aid in delivery of a baby at birth by being applied to vaginal tissue (i.e., the birth canal) of the baby's mother (col. 6, lines 53-54), and therefore one skilled in the art would reasonably expect the composition to form a lubricant layer between the birth canal surface and the item to be delivered.

### ***Conclusion***

No claims are allowed at this time.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Joanne Hama/  
Primary Examiner, Art Unit 1632